Abstract

A simple, specific, precise, and accurate reversed-phase HPLC method was developed and validated for simultaneous estimation of esomeprazole and tadalafil in pharmaceutical formulation. The separation was achieved by Hypersil BDS C₁₈ column (250 mm × 4.6 mm; 5.0 μm) using acetonitrile: 0.05 M potassium dihydrogen phosphate buffer at pH 6 adjusted with phosphoric acid acid at a flow rate of 1 mL/min. Detection was carried out at wavelength 285nm. The retention time of esomeprazole and tadalafil were 3.1, 3.7 min, respectively. The linearity was established over the concentration ranges of 60-180μg/mL and 40-120μg/mL with correlation coefficients 0.9998 and 0.9996 for esomeprazole and tadalafil, respectively. The mean recoveries were found to be in the ranges of 98–102% for esomeprazole and tadalafil. The proposed method has been validated as per ICH guidelines and successfully applied to the simultaneous estimation of esomeprazole and tadalafil in pharmaceutical formulation.